REMARKS

Claims 1-28 stand rejected under 35 USC § 103(a). Claims 1-28 are also rejected on the ground of nonstatutory obviousness-type double patenting. Claims 1-28 remain at issue.

Applicants respectfully request reconsideration of the application, withdrawal of all rejections and allowance of the application in view of the amendments above and remarks below.

*Amendments to the Claims*

Without prejudice to the Applicants' right to present claims of equal scope in a timely filed continuing application to expedite prosecution and issuance of the application, Applicants have amended independent claims 1 and 12.

The amendments to the claims do not introduce new matter. Applicants respectfully submit the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to reconsider the claims and allow all of the pending claims.

*Claim Rejections Under 35 USC § 103*

Claims 1-28 stand rejected under 35 USC § 103(a) as being unpatentable over Faithfull, U.S. Patent No. 6,041,777, in view of Bartus, U.S. Patent No. 6,514,482.

Claim 1 is directed to a device for producing a condensation aerosol. Claim 1 recites, among other elements, a heat source for supplying heat to a substrate to produce a substrate temperature greater than 300°C, and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less. Claim 1 also recites means for producing an air flow across the substrate producing aerosol particles by condensation. Claim 1 further recites that the device produces a condensation aerosol containing less than about 10% by weight drug composition degradation products and at least 50% of the drug composition of the film.

Claim 12 recites a method for producing a condensation aerosol and includes the step of heating to a temperature greater than 300°C a heat-conductive substrate having a drug composition film on the surface, the film comprising a therapeutically effective dose of a drug when the drug is administered in aerosol form. The drug composition film is substantially volatilized from the substrate in a period of 2 seconds or less. Air is flowed across the volatilized drug composition under conditions to produce a condensation aerosol containing less

than 10% by weight drug composition degradation products and at least 50% of the drug composition in the film.

Faithfull does not disclose or teach the device or method recited Applicants' claims. Faithfull also does not teach or disclose a heat conductive substrate having a surface and a film comprising a therapeutically effective dose of drug composition on the surface. Rather, Faithfull discloses the use of a warmed fluorochemical as a solvent for delivering the active compound "oxygen" to the lungs of the patient using a ventilation system. The active or therapeutic compound or drug in Faithfull is not heated to produce a vapor or condensed to form an aerosol. Instead, Faithfull requires the use of a wetted surface or wick to get the fluorochemical (solvent) to form a droplet. Moreover, the fluorochemical in the Faithfull reference is being delivered to the lung as a vapor and not as an aerosol. Faithfull does not disclose how to form an aerosol by vaporizing the drug composition by heating the substrate and condensing the vaporized drug composition. Nor does Faithfull disclose how to generate such an aerosol having 10% or less drug degradation products, or how to deliver at least 50% of the drug composition of the film. Nor does Faithfull disclose the claimed drug compositions and film thickness combinations recited in the various dependent claims.

The Office Action suggests that condensates by their nature have a high percentage of purity of the drug and less degradation products. See Office Action at p. 5, lines 10-12. Applicants respectfully disagree. The mere fact that an aerosol is formed by condensation does not mean that the aerosol will have a high percentage of drug and less degradation products.

Bartus does not cure the deficiencies of Faithfull nor render claims 1 or 12 obvious over Faithfull in view of Bartus.

Like Faithfull, Bartus fails to teach or suggest a drug composition film on a substrate or a heat source for supplying heat to the substrate to produce a temperature greater than 300°C and to substantially volatilize the drug composition film from the substrate in less than 2 seconds. Nor does Bartus teach producing aerosol particles by condensation or a device with these various elements producing a condensation aerosol containing less than about 10% by weight drug composition degradation products and at least 50% of the drug composition of the film. Rather, Bartus is directed to a method of delivering low tap density particles for the treatment of CNS disorders and in particular, Parkinson's disease, via dry power inhalers or metered dose inhalers. Nowhere does Bartus disclose or suggest forming an aerosol by vaporizing a drug composition

by heating a substrate and condensing a vaporized drug composition. Dry powder inhalers, metered dose inhalers, nebulizers, or instillation techniques do not vaporize the drug and then form a condensation aerosol of the drug. Additionally, in Bartus there is no disclosure of how one would form such an aerosol from drug to generate an aerosol having 10% or less drug degradation products and at least 50% of the drug composition of such a film. Bartus certainly does not disclose the claimed drug compositions and film thickness combinations.

Accordingly, the Office Action fails to establish a *prima facie* case of obviousness of independent claims 1 and 12 and claims 2-11 and 13-19, which are dependent from claims 1 and 12 respectively, as each and every element of the independent claims is not taught or disclosed by these references. Moreover, there would be no motivation to combine the references to achieve Applicants' presently claimed invention. Even if the cited references were combined, the claimed invention would not result because neither Faithfull nor Bartus disclose or teach all of the elements of the claimed device and method.

Independent claim 20 recites, *inter alia*, a heat-conductive substrate having an interior surface and an exterior surface and a drug composition film on the substrate exterior surface, the film comprising a therapeutically effective dose of a drug when the drug is administered in aerosol form. Claim 20 further recites a heat source for supplying heat to the substrate to produce a substrate temperature greater than 300°C and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less.

As set forth above, neither Faithfull nor Bartus is directed to a device or method for volatilizing a drug film applied to a substrate. Further, neither Faithfull nor Bartus teach or suggest the desirability of the heat source producing a substrate temperature greater than 300°C and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less. Faithfull and Bartus therefore cannot render obvious claim 20 nor claims 21-28, which are dependent from claim 20.

In light of the above-arguments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-28 under 35 USC § 103(a) over Faithfull in view of Bartus.

Claims 1-28 stand rejected under 35 USC § 103(a) as being unpatentable over Byron, U.S. Patent Publication No. 2004/0016427 in view of Bartus.

As conceded by the Examiner, Byron is directed to an apparatus and method for generating an aerosol by supplying a liquid to a tube and heating the tube such that the material volatilizes an expands out of an open end of the tube. Thus, Byron fails to teach a drug composition film on a substrate or a heat source supplying heat to the substrate to produce a temperature greater than 300°C and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less. Moreover, Byron contains no teaching that the apparatus of Byron produces a condensation aerosol containing less than about 10% by weight drug composition degradation products and at least 50% of the drug composition of the film. Furthermore, as discussed above, Bartus does not overcome these deficiencies of Byron. Thus, the Office Action fails to establish a *prima facie* case of obviousness of claims 1-19.

Claim 20 is directed to an assembly for use in a condensation aerosol device and recites a drug composition film on a substrate exterior surface, the film comprising a therapeutically effective dose of a drug when the drug is administered in aerosol form. Also recited is a heat source for supplying heat to the substrate to produce a substrate temperature greater than 300°C and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less.

Byron does not teach a drug composition film on a substrate or heating the substrate to greater than 300°C to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less. As discussed above, Bartus fails to teach these elements as well. Thus, Byron in view of Bartus does not establish a *prima facie* case of obviousness, as each and every element of claim 20 is not taught or disclosed by the references.

In light of the above arguments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-28 under 35 USC § 103 over Byron in view Bartus.

*Double Patenting*

Claims 1-28 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 7,090,830, in view of Byron. Further, claims 1-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending application No. 10/633,877. Finally, claims 1-28 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 10/437,643;

10/057,197 and 10/057,198. In each instance, the Examiner states claims 1-28 and the claims of the cited references "are not patentably distinct from each other because the examined claims would have been obvious over the reference claims."

In order to remove the rejection Applicants agree to file terminal disclaimers with regard to the patents and applications once patentable subject matter has been determined. Applicants respectfully request acknowledgement that submission of such terminal disclaimers will overcome nonstatutory obviousness-type double patenting rejection of claims 1-28.

*Conclusion*

Applicants respectfully submit that the Examiner's concerns have been addressed by the amendments above. Applicants accordingly request the Examiner withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance or help to resolve outstanding issues relating to the prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

Respectfully submitted,

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